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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2004N-0525]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reports of corrections and removals.

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910-0359)—Extension**

The collection of information required under the reports of corrections and removals, part 806, (21 CFR part 806) implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105-115).

Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, within 10 working days of initiating such correction or removal.

Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

Respondents to this collection of information are manufacturers and importers of medical devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 806.10         | 482                | 1                             | 482                    | 10                 | 4,820       |
| Total          |                    |                               |                        |                    | 4,820       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

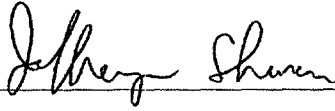
| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 806.20         | 143                  | 1                                  | 143                  | 10               | 1,430       |
| Total          |                      |                                    |                      |                  | 1,430       |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

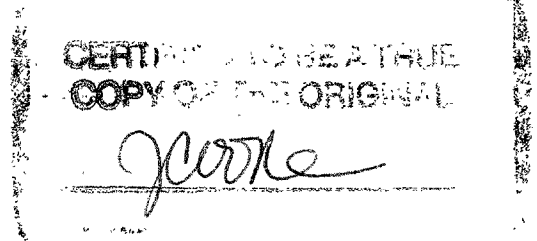
In 2001, when preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under part 7 (21 CFR part 7) (the agency's recall provisions). FDA has determined that estimates of the reporting burden in §§ 806.10 and 806.20 should be revised to reflect

a reduction of 29 percent for reports and records submitted under part 7 due to a decrease in recall actions. The time needed to collect information has been reduced by 4 hours per record due to the implementation of a computerized program for information collection requirements in part 806.

Dated: 12/6/04  
December 6, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy..



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